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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,262	08/27/2003	Yerramilli V.S.N. Murthy	61635-5016	6595

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KENYON & KENYON LLP  
1500 K STREET N.W.  
SUITE 700  
WASHINGTON, DC 20005

EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/650,262

Applicant(s)

MURTHY ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 44-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 44-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 6, 11, 13 and 14 have been amended and claims 15-43 have been canceled. New claims 45-70 have been added. Claims 1-14 and 44-70 are pending in this application.

Applicants' arguments filed October 6, 2006 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al. U.S. Patent No. 5,719,197.

Kanios et al. teach compositions comprising a solvent and an active agent and a carrier. The solvents include fatty acids such as linoleic acid (column 4, lines 9-12) (identified as a water immiscible solvent in, for example, claim 11), fluoxetine (column 19, line 4) and 2-Hexyl Decanoic acid (column 30, line 24) (identified as a lipophilic counterion in, for example, claim 8). It does not recite these agents specifically as a "lipophilic counter ion" and "water immiscible solvent", however, "products of identical chemical composition (i.e. linoleic acid as a water immiscible solvent and decanoic acid

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as a lipophilic counterion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. their activity as a lipophilic counterion and a water immiscible solvent) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). Therefore it would have been obvious to employ fluoxetine, decanoic acid and linoleic acid in a composition motivated by the teaching of Kanios et al. who teach, *inter alia*, the same composition.

### ***Response to Arguments***

In response to applicant's argument that Kanios et al. does not disclose each and every feature of the invention recited in claim 1. Applicant has amended claim 1 to include the phrase "for oral administration or an injectable composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant asserts that the compositions would not be suitable for inclusion in a composition for oral administration or parenteral

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administration. However, claim 1 does not exclude the agents in the composition of Kanios et al. Regarding the suitability or safety of the agent administered orally or parenterally, Applicant appears to confuse the requirements for patentability with those of receiving FDA approval. See e.g. In re Anthony, 414 F.2d 1383, 1395, 162 USPQ 594, 604 (CCPA 1969). Consequently, this argument does not raise an issue of material fact.

### ***Terminal Disclaimer***

The terminal disclaimer filed on October 6, 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 6887487 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Note: there are two claims indicated as claim 53.

The second misnumbered claim 53 has been renumbered 54.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 45-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "over time" in claim 1 is a relative term which renders the claim indefinite. The term "over time" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has not provided any information as to what is meant by the phrase "a composition for oral administration or an injectable composition that releases the active compound over time when administered to the mammal". Is it one second or is it one hour? Both are designations of units of time.

Claim 55 recites the limitation "the composition of claim 53 wherein the pharmaceutically acceptable water immiscible solvent is selected from the group consisting of one or more of safflower oil, castor oil, linoleic acid and isopropyl myristate". There is insufficient antecedent basis for this limitation in the claim because there is not a water immiscible solvent recited in claim 53. Amending the claim to depend from claim 54 would obviate the rejection.

Claims 2-14, 45-54 and 56-57 are rejected as being indefinite to the extent that they read on the rejected base claims.

***New Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 44, 45-48, 50, 51, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shojaei et al. U.S. Patent No. 7,011,846 B2.

Shojaei et al. teach a composition for oral administration comprising an active compound such as fluoxetine (column 5, line 53) and the lipophilic counter ion, decanoic acid (see tables 1-3) and water immiscible solvent (see table 1, castor oil). Shojaei et al. differs in that it does not specifically identify the components and "lipophilic counter ions" and "water immiscible solvents". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). It would have been made obvious to one of ordinary skill in art at the time it was made to combine an active agent such as fluoxetine with a water

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immiscible solvent such as castor oil and a lipophilic counter ion such as decanoic acid motivated by the teaching of Shojaei et al. that the composition is successful in increasing the physical stability of the hydrophobic active agents (see abstract)

Claims 1-5, 11, 12, 44, 45-48, 50, 51, 54, 55, 58-61, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. U.S. Patent No. 6,174,540 B1.

Williams et al. teach an injectable formulation comprising *inter alia* an active agent, such as antibiotics that are insoluble in water (oil soluble) and a water immiscible solvent, hydrogenated castor oil, and capric acid (a.k.a. decanoic acid) (see abstract). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). It further differs in that it does not specifically teach the



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active agents in claims 4, 47 and 60, but it is noted that the long acting injectable agents of the patent are intended to solublize and release slowly an insoluble drug by solubilizing the agent in a water immiscible solvent (castor oil) and a lipophilic counterion (capric acid, a.k.a. decanoic acid) as in the instant claims. It would have been made obvious to one of ordinary skill in art at the time it was made to combine a water insoluble active agent such as the recited antimicrobials (see column 1, lines 50-60) with a water immiscible solvent such as hydrogenated castor oil and a lipophilic counter ion such as capric acid (decanoic acid) motivated by the teaching of Williams et al. that the composition is a successful carrier for injectable agents that result in a long acting injection (see abstract).

Claims 1-8, 11, 12, 14, 44-51, 54, 55, 57-64, 67, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. U.S. Patent No. 6,309,663 B1.

Patel et al. teach a pharmaceutical composition for oral or parenteral use (column 41, lines 44-54) comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties

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are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). It would have been made obvious to one of ordinary skill in art at the time it was made to combine an active agent such as gentamycin and fluoxetine (see column 30, lines 3 and 36) with a water immiscible solvent such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). motivated by the teaching of Patel et al. that the composition is a successful carrier for oral and injectable agents.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 44-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65-138 of copending Application No. 11/088922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 65 requires an active agent, a lipophilic counter ion and a pharmaceutically acceptable solvent, however, the claims contain the same elements as recited in the instant claims, e.g., active agents such as tilmicosin, lipophilic counter ions such as decanoic acid and solvents such as linoleic acid. The instant claims require elements such as e.g. active agents such as tilmicosin, a lipophilic counter ion such as decanoic acid and a water immiscible solvent such as linoleic acid (note linoleic acid is listed in the instant claims as a lipophilic counter ion and as a water immiscible solvent). None of the instant claims recites that specific combination, but instant claims 1-14 and 44-70 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that

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they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical composition, the properties applicant discloses and/or claims (i.e. water immiscible solvent and lipophilic counterion) are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

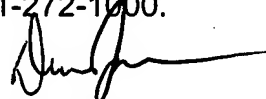
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Donna Jagoe  
Patent Examiner  
Art Unit 1614

April 25, 2007

~~ARDIN H. MARSCHEL~~  
~~SUPERVISORY PATENT EXAMINER~~

*Ardin H. Marschel 4/30/07*  
ARDIN H. MARSCHEL  
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